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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/511,882
Filing Date: October 19, 2004
Appellant(s): KUKLINSKI ET AL.

Travis M. Wohlers
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 04/16/2010 appealing from the Office action mailed 09/23/2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 9, 10, and 14-22 are pending and rejected in the application.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

WO 01/97634	Fuchs et al.	12-2001
SU 1740002	Sharmanov et al	06-1992

Bühlbäcker, Alexander, "Zur Verwendbarkeit von Stutenmilch, Kumyss und Eselmilch als Diatetika und Heilmittel unter besonderer Berücksichtigung der Bedürfnisse des Säuglings und des Frühgeborenen", 1996, Verlag Dr.Hansel-Hohenhausen, pages 367-376.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 9, 10, and 14-22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al (WO 01/97634 A1) in view of Institut Regionalnykh Problem Pitaniya (SU 1740002 A1-from IDS, relevance explained in Russian Search Report) or Bühlbäcker (Verlag, 1996, relevance explained in Appellant's disclosure, page 8).

Fuchs teaches an oral composition comprising highly unsaturated fatty acids on a biologically inert matrix (p.9) and drying the composition at a pressure of 10-30 mbar and a temperature of 30-36 °C (p.12). The reference also teaches that it is advantageous to add mare's milk before drying (p.15). It is also taught that it is especially advantageous if the composition is applied on a highly dispersed silicon dioxide matrix (p.12). The composition taught by the reference also contains linolenic acid (p.20), which is a vegetable essential fatty acid. Vitamin B₁ is present in mare's milk and therefore inherently present in the composition. Fuchs teaches that highly unsaturated fatty acids are of a high biological and nutrition-medical relevance, especially for skin metabolism, neurodermatitis and psoriasis (p.3) and that the composition taught contains at least one unsaturated fatty acid. The disclosure of the skin disorders, neurodermatitis and psoriasis, and their connection with the need for the highly unsaturated fatty acids would indicate that administration of the referenced composition, which contains highly unsaturated fatty acids, would be necessary.

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In addition, the reference does teach where the subject is human and that the dry concentrates of mare's milk have beneficial effects on humans (p.15).

Russian patent (SU 1740002 A1) teaches the use of specially prepared mare milk (kumiss) for oral intake for the treatment of neurodermatitis and eczema (as described in Russian Search Report-English Translation page 2).

Alexander Bühlbäcker describes the use of native mare's milk as a food additive in the treatment of neurodermatitis (as described in the Spec page 8).

Therefore, it would have been obvious to one of ordinary skill in the art to use the composition of Fuchs that contains mare's milk for the treatment and prevention of dry skin diseases such as neurodermatitis and psoriasis since the highly unsaturated fatty acids in the composition are taught by Fuchs to be important for skin metabolism and these skin disorders (p.3) and mare's milk contains highly unsaturated fatty acids. One of ordinary skill in the art would have also been motivated by the Russian patent and Bühlbäcker to use the composition of Fuch's for these skin diseases because mare's milk (found in an embodiment of Fuch's composition) is known to be used for the treatment of neurodermatitis and like skin diseases. One of ordinary skill in the art would have had a reasonable expectation of success since Fuchs provides a composition that ensures a fine surface distribution of the oil particles so that sufficient quantities of unsaturated fatty acids are included (p.7) and teaches embodiments including mare's milk. One of ordinary skill in the art would have also had a reasonable expectation of success since Fuchs does NOT teach that the embodiment of the method including mare's milk is not intended for the treatment

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of neurodermatitis or psoriasis, nor does Fuchs indicate that the embodiment including mare's milk is limited to only certain disorders.

Therefore, the combined teachings of Fuchs and the Russian patent (SU 1740002 A1) or Bühlbäcker render obvious Appellant's invention as claimed.

(10) Response to Argument

Appellant argues that the currently claimed method of treating neurodermatitis or psoriasis is non-obvious over the cited references because the results of the claimed method were unexpected. Appellant asserts that the Bühlbäcker reference required a minimum treatment time of 10 months and was ineffective if given alone. Appellant asserts that the claimed method unexpectedly gives results in one month. Appellant asserts that since mare's milk does not contain alcohol (as koumiss-fermented mare's milk- does), one could not have predicted a similar benefit of mare's milk based on the properties of koumiss cited in the SU 1740002 reference (translation page 4). Appellant asserts that the unexpected results of the claimed method could not have been predicted by the Fuchs reference or the SU 1740002 because there is no data regarding treatments with either native mare's milk or a dried mare's milk concentrate and because Fuchs does not specifically disclose or suggest using the reference composition as a treatment for neurodermatitis or psoriasis.

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This is not found persuasive because of several reasons. First, the obviousness rejection relies upon the teaching of Bühlbäcker and SU 1740002 to add additional motivation to the teaching of Fuchs that applying the composition of Fuchs to the treatment of neurodermatitis and psoriasis would be obviously beneficial. One of ordinary skill in the art would expect the composition of Fuchs to perform better than the composition of Bühlbäcker because Fuchs teaches that the reference method is significantly improved over the prior art. Fuchs teaches that the reference method produces a composition in which many of the prior known disadvantages are circumvented and in which the high health promoting value of the unsaturated fatty acids can be maintained (page 7). These unsaturated fatty acids that Fuchs maintains are very important for skin metabolism – specifically neurodermatitis and psoriasis (page 3 line 9). It is this passage that provides evidence that Fuchs intended for this improved composition (that was suggested to also include mare's milk on a biologically inert, disperse matrix) to be used in the treatment of neurodermatitis and psoriasis. Clearly, one of ordinary skill in the art would have expected the composition of Fuchs to perform better than the Bühlbäcker composition because of the improved formulation and the inclusion of additional health promoting ingredients.

Second, while the SU 1740002 reference attributes some of the secondary properties of koumiss to its alcohol content, the primary skin benefits are owed to the fact that koumiss has a full value amino acid formulation and the koumiss albumins are represented by a readily available albumin fraction which

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remedies the albumin loss that occurs in connection with a cutaneous and inflammatory process (festering, desquamation) (page 4). Thus it is the albumins (proteins) in the mare's milk and not the alcohol from the fermentation that are suggested as responsible for the effectiveness of koumiss in the treatment of the primary skin symptoms of neurodermatitis or psoriasis. In addition, not only would SU 1740002 motivate one of ordinary skill in the art to apply the Fuchs composition containing mare's milk to the treatment of skin diseases such as neurodermatitis or psoriasis, there would have been a reasonable expectation of attaining results in about a month because SU 1740002 teaches that fermented mare's milk orally administered to patients gives results in less than one month (page 3) and Fuchs teaches that the mare's milk dried on a biologically, inert, disperse matrix provides increased stability and high health promoting values as well as containing the unsaturated fatty acids important for treating neurodermatitis or psoriasis. Therefore treatment results in one month are not unexpected for an improved, stable composition of mare's milk.

In conclusion, the teaching of the Fuchs reference provides the same composition as claimed by Appellant and teaches that this composition (the composition disclosed in the reference) is important for skin metabolism and suggests that it be administered as a skin treatment for neurodermatitis or psoriasis (see page 3 of translation). The teachings of SU 1740002 and Bühlbäcker provide additional motivation to select the specific skin conditions from the list of conditions cited in Fuchs with a reasonable expectation of success in using a composition containing mare's milk in the treatment of

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neurodermatitis or psoriasis. In addition, the achievement of results in about a month are not deemed to be unexpected in view that the Fuchs' composition is taught to be improved over prior compositions and the SU 1740002 reference teaches that results in less than a month are attained by using fermented mare's milk (which contains the same albumins as mare's milk which are primarily responsible for the improved skin results).

Appellant argues that a review of the translation of the Fuchs reference indicates that word "improve" or "improved" was used only once, and that this was in regard to improved shelf life of the product. Appellant asserts that this is not a sufficient motivation for the establishment of obviousness.

This is not found persuasive because a closer review of the translation reveals that other terms are used to convey to the reader that the Fuchs reference disclosed a composition that was improved over the compositions of the prior art. For example, the Fuchs reference states that "it is the object of the invention to make available a process for producing a concentrate from unsaturated fatty acids, in which the above mentioned disadvantages are circumvented, and in which however the high health promoting value of the unsaturated fatty acids can be maintained" (page 7 of the translation). Also the use of the phrase "a further advantage" (page 10 of the translation) with regard to the qualities of the reference composition implies that the composition was an improvement over the prior art compositions as well. The addition of mare's milk was also specified as an advantage as well (page 15 of the translation).

Appellant argues that much of the Examiner's arguments are based on presumed intentions, not facts. Appellant asserts that the Examiner makes conclusionary assertions that Fuchs "clearly intended" to include mare's milk in the formulation and use that formulation in the treatment of neurodermatitis and psoriasis. Appellant argues that factual findings made by the Examiner are the necessary underpinnings to establish obviousness. Appellant asserts that the Examiner's presumptions of the intentions of the Fuchs reference have not been supported by factual findings.

This is not found persuasive because the Fuchs reference explicitly states the advantages of the composition (page 10 of the translation) as well as the advantages of including milk such as mare's milk in the composition (page 15 of the translation) and the importance of using an unsaturated fatty acid composition (such as the reference composition) for the treatment of neurodermatitis and psoriasis (page 3 of the translation) and the suggestion to formulate the composition in different medicament forms (page 23 of the translation). These express statements made in the Fuchs reference provide factual evidence that support the conclusion that the composition of the Fuchs reference was intended to be used in the treatment of different skin disorders, specifically neurodermatitis and psoriasis.

Appellant argues that there are no identified facts that support the Examiner's conclusion that a person of ordinary skill in the art would have expected that the mare's milk concentrate dried on a biologically inert, disperse

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matrix would be more effective at treating neurodermatitis or psoriasis than the native mare's milk disclosed in Bühlbäcker.

This is not found persuasive because one of ordinary skill in the art would expect the composition of Fuchs to perform better than the composition of Bühlbäcker because Fuchs teaches that the reference method is significantly improved over the prior art. Fuchs teaches that the reference method produces a composition in which many of the prior known disadvantages are circumvented and in which the high health promoting value of the unsaturated fatty acids can be maintained (page 7). These unsaturated fatty acids are what Fuchs maintains are very important for skin metabolism –specifically neurodermatitis and psoriasis (page 3). Clearly Fuchs intended for this improved composition (that was suggested to also include mare's milk on a biologically inert, disperse matrix) to be used in the treatment of neurodermatitis and psoriasis. Clearly, one of ordinary skill in the art would have expected the composition of Fuchs to perform better than the Bühlbäcker composition because of the improved formulation and the inclusion of additional health promoting ingredients (the additional unsaturated fatty acids).

Appellant argues that to improve the efficacy of mare's milk in treating neurodermatitis and psoriasis, the teachings of Bühlbäcker and SU 1740002 would suggest to a person of ordinary skill in the art that one would need to ferment the mare's milk. Appellant asserts that the drying process of the Fuchs reference would be incompatible with the teachings of SU 1740002 regarding the sedative effect of the alcohol in the koumiss. Appellant asserts that the proposed

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modification or combination of the prior art would change the principle of the operation of the prior art invention being modified or render it unsatisfactory for its intended purpose and thus the teachings of the references are not sufficient to render the claims *prima facie* obvious.

This is not found persuasive for several reasons. First of all, the teachings of Bühlbäcker and SU 1740002 are relied on in the obviousness rejection to provide motivation for one of ordinary skill in the art to select those embodiments in the Fuchs reference that contain mare's milk for the treatment of skin disorders such as neurodermatitis and psoriasis. The fact that mare's milk had been previously used to treat these specific disorders with some measure of success provides a motivation to select mare's milk over the other types of milk listed as acceptable in the Fuchs reference composition as well.

Second, while the SU 1740002 reference attributes some of the secondary properties of koumiss to its alcohol content, the primary skin benefits are owed to the fact that koumiss has a full value amino acid formulation and the koumiss albumins are represented by a readily available albumin fraction which remedies the albumin loss that occurs in connection with a cutaneous and inflammatory process (festering, desquamation) (page 4). Clearly, the albumins (proteins) in the mare's milk, not the alcohol from the fermentation, are suggested as responsible for the effectiveness of koumiss in the treatment of the primary skin symptoms of neurodermatitis or psoriasis.

Third, any loss of a sedating effect caused by the drying of the mare's milk in the composition of the Fuchs reference could easily be compensated by the

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addition of other sleep promoting agents (such as antihistamines) if needed.

Fuchs specifically suggests that the addition of other medicaments to the composition is acceptable as well (page 16 of the translation). Therefore the combination of references does not change the operation of the Fuchs reference composition nor render it unsatisfactory for its intended purpose as Appellant asserts.

The declaration under 37 CFR 1.132 filed 07/17/2008 is insufficient to overcome the rejection of claims 9-10 and 14-22 based upon obviousness over Fuchs et al (WO 01/97634) in view of SU 1740002 or Buhlbacker under 35 USC 103 (a) as set forth in the last Office action because:

It refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

The declaration describes the use of a dried mare's concentrate as formulated by Appellant's disclosure (page 19 line 7 to page 20 line 1). This formulation includes many elements that are not included in the claimed invention such as additional ingredients (stabilizers, oils, minerals, vitamins and trace elements in Table 1) as well as the added treatments of ointments and oil baths. Therefore the evidence is not commensurate in scope with the invention as claimed.

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In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Laura Schuberg/
Examiner
Art Unit 1657

Conferees:
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